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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,243	09/26/2001	Curt R. Eyster	LIFE063	8576
7590	06/15/2004		EXAMINER	
LifeScan , Inc . 1000 Gibraltar Drive , M/S 3D ATTN: Mayumi Maeda Milpitas, CA 95035			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/963,243	Applicant(s) EYSTER ET AL. <i>[Signature]</i>
	Examiner Lyle A Alexander	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 10 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hirayaja et al (USP 6,299,838).

Hirayaja et al teach a test device and use with a colorimeter to make optical determinations from a color liquid such as blood. Figure 1 teach a first surface(1) and an opposite surface(5) having an aperture(51) in surface(5) that receives the sample. In columns 5-6 lines 60 – 16 respectively teach the surface(5) can be black in color having a reflectance of 5.3% at a wavelength of 640 nm. The Office has read the claimed top layer on surface(1), the bottom layer on surface(5).

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Phillips et al. (USP 5,843,692).

Phillips et al. teach a test strip and spectrometer for the measurement of analytes in blood in the range of 635-700nm. In column 8 lines 5+ teach a

preferred method of sample acquisition is by finger prick which results in a sample of 5-10 microliters of blood. Column 15 lines 53-58 a reflectance range of 0-100% reflectance that has been read on the less than about 12 %. Further in column 11 lines 9+ teach the test strip is optimally guided into the spectrophotometer by using a notch(15). The notch is advantageous because the slide will repeatably arrive at the same location to assure high reproducibility of test results. The notch is further advantageous because the user can not place the wrong end into the spectrometer and obtain a spurious result.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirayaja et al.

See Hirayaja et al supra.

Hirayaja et al teach a sample size of 20 microliters and are silent to the claimed 5 microliter sample volume.

The court decided In re Yount (80 USPQ 141) that the size of an article under consideration is not ordinarily a matter of invention. In this case the size of the device dictates the volume of sample that would be required (e.g. a larger device would require a larger sample, etc.). Further, it is desirable in the field of analytical testing to use the minimal volume of sample to minimize the amount of sample needed. Smaller sample can be obtained in a more comfortable manner by finger prick as opposed vein puncture. Also the smaller sample obtained by finger prick do not need specialized technicians and can be done by the patient.

It would have been within the skill of the art to modify Hirayaja et al. to require a smaller volume of blood, such as 5 microliter, to gain the above advantages of using a smaller sample in light of the teaching of Yount that size is not ordinarily a matter of invention.

Claims 3-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirayaja et al in view of Phillips et al. (USP 5,843,692).

See Hirayaja et al. supra.

Hirayaja et al. is silent to the claimed 5 microliter sample volume and use of a "notch" in the test strip.

Phillips et al. teach a test strip and spectrometer for the measurement of analytes in blood in the range of 635-700nm. In column 8 lines 5+ teach a preferred method of sample acquisition is by finger prick which results in a sample of 5-10 microliters of blood. Further in column 11 lines 9+ teach the test strip is optimally guided into the spectrophotometer by using a notch(15). The notch is advantageous because the slide will consistently arrive at the same location to assure high reproducibility of test results. The notch is further advantageous because the user can not place the wrong end into the spectrometer and obtain a spurious result.

The court decided In re Yount (80 USPQ 141) that the size of an article under consideration is not ordinarily a matter of invention. In this case the size of the device dictates the volume of sample that would be required (e.g. a larger device would require a larger sample, etc.). It is desirable in the field of analytical testing to use the minimal volume of sample to minimize the amount of sample needed. Smaller sample can be obtained in a more comfortable manner by finger prick as opposed vein puncture. Phillips et al. teach it is preferred to use a finger prick to obtain the sample in the volume range of 5-10 microliters.

It would have been within the skill of the art to modify Hirayaja et al. in view of Phillips et al. incorporate a notch and use a finger prick to collect a minimal blood volume of 5 microliters to gain the above advantages.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. alone or further in view of Hirayaja et al.

See Phillips et al. and Hirayaja et al. supra.

These Phillips et al. teach a reflectivity of from 0 to 100%.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. Phillips et al. teach reflectivity in the range of 0 to 100% and all of the taught range is a result effective variable because it is contemplated by the reference.

It would have been within the skill of the art to modify Phillips et al. and select a reflectivity range of less than about 12 % as optimization of a result effective variable.

Hirayaja et al. teaches in column 4 lines 64-67 that black is a preferred color because it absorbs light over a broad range of wavelengths and can be applied to simultaneous measurements of a plurality of items. Columns 5-6 lines 60 – 16 respectively teach the surface(5) a black surface will have a reflectance of 5.3% at a wavelength of 640 nm which reads on the claimed reflectivity of less than about 12% at wavelengths 600-730 nm .

It would have been within the skill of the art to modify Phillips et al. in view of Hirayaja et al. and use a black surface to gain the above advantages.

Response to Arguments

Applicant's arguments filed 4/1/04 have been fully considered but they are not persuasive.

Applicants state Hirayaja et al. fails to teach the reagent layer underlying the receiving aperture. The instant claim language of "underlying" is sufficiently broad to read on Hirayaja et al. who also teaches the reagent underneath or underlying the aperture. Applicants should use language to better describe the reagent layer as being adjacent to and in physical contact with as well as underlying the aperture.

Applicants state the remaining 35 USC 103 rejections depend on the 35 USC 102 rejection and should be allowable for the same reasons as argued for the 35 USC 102 above. The Office does not believe the claim language defines over Hirayaja et al. under 35 USC 102 for the above reasons and therefore does not define over Hirayaja et al. under 35 USC 103 either for the reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander
Primary Examiner
Art Unit 1743
